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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/962,421	10/31/1997	EUGENIO A. CEFALI	20720-95585	8845

7590 06/14/2006

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EXAMINER	
HAWES, PILI ASABI	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/962,421	CEFALI ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Summary

Receipt of the Remarks and Amendments filed 03-15-2006 is acknowledged. Claims 1-4 are pending in this action. Claims 1-4 are rejected.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

The later-filed application must be an application for a patent for an invention, which is also disclosed, in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/814974 now US Patent 6129930, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The instant claims 1-4 recite an intermediate release composition comprising nicotinic acid, in which the nicotinic acid is released over a stair stepped absorption profile. However, the particular stair stepped absorption profile recited by instant claims are not supported by the parent application. Thus, claims 1-4 do not

receive benefit of the priority date of the parent application. The only reference to a rate of release that the claims or the specification make is a sustained release rate in which between about 2-25% of the nicotinic acid is released per hour. This general teaching does not support the specific recitation of up to 19% of nicotinic acid absorbed between 1-4 hours in the first phase, between 78-100% absorbed between 5-9 hours in the second phase, and between 86-100% absorbed by about 9 hours in the third phase.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6406715.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As discussed above, Applicant does not receive benefit of the filing date of the CIP parent US 6129930. Thus the filing date of the instant application is 10-31-1997. The filing date of the prior art reference is 10-31-1997, and the prior art reference claims benefit of priority applications dated back to 09-20-1993. The reference names one inventor in common with the instant application, while the instant application names two inventors. Thus this prior art reference is "by another" and has a prior effective U.S. filing date, which is earlier than the instant applications filing date.

Cefali teaches compositions that afford intermediate release of nicotinic acid, and that are used for the treatment of hyperlipidemia (col. 1, lines 20). The instant claims are drawn to a method of treating hyperlipidemia with an intermediate release composition of nicotinic acid. The prior art reference also teaches the composition to have a stair-stepped absorption profile (col. 5, line 31). The reference further teaches that the composition releases "at least the majority" of the composition between 5 and 9 hours (col. 5, lines 17-20). The reference also describes three separate absorption phases: A, B and C (col. 8, lines 1-13). Phase A occurs within 1-4 hours, phase B between 4-8 hours, and phase C between 5-9 hours (col. 8, lines 15-19). Table 1 discloses that up to about 19% of the composition is absorbed in phase A, and between 78-100% is absorbed in phase B, with the remainder being absorbed in phase C (col. 8, lines 20-25). Table 1 shows that 90.7 % is absorbed in phase B, this is about 91% as is recited in instant claims. Table 1 also discloses the same absorption rate ranges for each phase as claimed in claim 3. Table 1 also discloses the limitations of claim 4, in that the

% dose absorbed in phase A was 3.3% in 2.3 hours, and in phase B was 19% in 7.3 hours.

Response to Arguments

Applicant's 37 CFR 132 Declaration filed 03-15-2006 submitted to overcome the 102 (e) rejection made over US 6406715 (Cefali) has been considered but is not persuasive. Dr. Cefali declares that the work in the instant application was derived from the same work that formed the basis for the invention set forth in US 6406715. Dr. Cefali also declares that the instant body of work and cited reference US 6406715 are derived from the parent application US 6129930. It is noted that the sole inventor on the parent application US 6129930 is Dr. David Bova. US 6129930 discloses the same composition and the same method as claimed in the instant application. Thus it is unclear what portion of the invention was Dr. Cefali's work alone. As the inventive entity in the instant application is both Dr. Cefali and Dr. Bova, this constitutes a different inventive entity over Dr. Cefali or Dr. Bova alone. Additionally, priority to US 6129930 has been denied since the disclosure does not enable the stair stepped or sigmoidally shaped absorption profile claimed in the instant application. Thus the claimed absorption profile of the instant claims constitutes new matter for which the disclosure of US 6129930 does not lend support. It would appear that the instant invention is a work derived from both the work of US 6406715 and US 6129930, thus it is unclear how Dr. Cefali can certify to be the sole inventor of the instant invention, and the invention of US 6406715 and thus claim that the work of US 6406715 is not by another, because the work of the instant application is done by the inventive entity " Dr. Bova and Dr. Cefali" ,

and the work of US 6406715 is by the inventive entity "Dr. Cefali". Thus US 6406715 is "by another" and the 102 (e) made over Cefali is maintained.

Upon further consideration the following are further grounds of rejection:

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-4 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-17, 34-132 of prior U.S. Patent No. 6129930. This is a double patenting rejection.

The patented claims recite a method of treating hyperlipedmia by administering a sustained release composition of nicotinic acid once per day. It is noted that that instant claims are directed toward an intermediate release formulation, however the structural components of the formulation in both the patent '930 and the instant disclosure are identical. Thus the composition of the patent and the instant claims is the same. Further the positive method step of treating hyperlipedemia with the identical composition would be identical, thus even though the claims differ in wording, the composition being administered is the same and method step of administering the composition once per day is the same. Thus the claimed subject matter is identical.

Claims 1-4 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-27 of prior U.S. Patent No. 6676967. This is a double patenting rejection.

The patented claims recite the same positive method step and that is orally administering a once per day intermediate release formulation of nicotinic acid. Applicants attention is drawn to Table 1B which discloses the same exact ingredients as are disclosed in the instant application's Table 1B. Thus the method of administering the same composition makes the scope of the instant claims and patented claims identical, and thus this constitutes statutory double patenting.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-148 of U.S. Patent No. 6129930.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the method claims presented define the composition being administered structurally, instead of functionally the way the composition is defined in the instant application. However as was discussed above the composition ingredients are identical in both the patent disclosure and the specification disclosure. Thus the composition being administered is identical and even though the method of administering the identical composition is claimed in functional language with regard to the release profile in the instant application and claimed with structural language with respect to the patented claims the method of administering the same composition would still be obvious to one of ordinary skill in the art. It would further be obvious to administer the composition of the patented claims in the same method as taught in the patented claims, and it would be an inseparable function of the composition disclosed in the patented claims to exhibit the release profile as claimed in the instant application because the compositions in both the patent and the instant application are identical. The fact that the language of the patented claims describe the composition as sustained release and the instant application defines it as intermediate release is noted, however the ingredients that make up the composition are identical in both the patent and the instant application (see table 1B in the patent and table IB in the instant disclosure).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6406715. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are to an intermediate release nicotinic acid

once a day formulation. It would be obvious to one of ordinary skill in the art to administer the oral once a day nicotinic acid formulation to treat hyperlipidemia. The composition ingredients of the instant formulation and the patented formulation are identical (see table 1B of both the patent and the instant specification).

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6746691. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are to an intermediate release nicotinic acid once a day formulation. It would be obvious to one of ordinary skill in the art to administer the oral once a day nicotinic acid formulation to treat hyperlipidemia. The composition ingredients of the instant formulation and the patented formulation are identical (see table 1B of both the patent and the instant specification).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for orally administered antihyperlipidemia compositions which comprise 30-90% parts of nicotinic acid, and 5-50% parts of hydroxypropylmethylcellulose, does not reasonably provide enablement for other nicotinic acid formulations that exhibit intermediate release with other ingredients other

than those disclosed in the instant specification. Page 8, lines 5-16 disclose the ingredients of the compositions. Further Table 1B disclose specific formulations for which the claims are enabled, however formulation comprising other polymers not specifically disclosed in ranges and amounts outside the ranges disclosed in the specification are not enabled. The instant claims do not include any specific structural limitations that would define the composition commensurate in scope with the disclosure of the instant invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. One of ordinary skill in the art would not know without undue experimentation how to select an intermediate release nicotinic acid formulation for once a day administration to treat hyperlipidemia that would exhibit the same release profile, because the claims do not disclose any structural features of the composition. Thus any composition that comprises nicotinic acid in an intermediate release formulation would satisfy the requirements of the claims, and the specification is not enabling for all intermediate release formulations.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by Bova US 6129930.

Bova discloses a nicotinic acid formulation, which comprises 30-90% parts of nicotinic acid, and 5-50% parts of hydroxypropylmethylcellulose (col. 3, lines 5-16). Examiner notes this is the same as the ingredients disclosed in the instant specification on page 8, lines 5-16. Bova further teaches a method of administering said compositions in once per day doses for the treatment of hyperlipidemia (col. 3, lines 25-30). Bova discloses specific formulations in table 1B. Examiner notes the instant disclosure discloses the same formulation in table 1B. Thus the composition of Bova, since it comprises the same ingredients, in the same amounts as that claimed in the instant application would be expected to exhibit the same stair stepped or sigmoidally shaped absorption profile as claimed in the instant invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P.A. Hawes
Examiner-1615

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